

Appl. No. : 10/642,445  
Filed : August 15, 2003

### REMARKS

Claims 32-51 and 58-78 stand rejected. Applicant has amended Claims 32, 44, 49, 58, and 60. Thus, Claims 32-51 and 58-78 are pending in the application and are presented for reconsideration and further examination in view of the amendments and the following remarks.

#### Interview Summary

Applicant would like to thank the Examiner for taking the time to meet and discuss the outstanding Office Action in a personal interview with counsel for Applicant on June 10, 2005. During the interview, proposed amendments to the claims were discussed. In regard to Claim 32, Applicant's counsel proposed an amendment to define further that the channel is configured to retain at least a portion of the medical article within the body member with the retained portion extending entirely through the channel. This retained portion is further inhibited from contacting a patient's skin. Similar language is being proposed for amendments to Claims 44, 49, 58, and 60.

Applicant's counsel and the Examiner also discussed the fact that Claim 32 is directed to a retainer having structural features that are described with respect to a retained medical article. These features serve to structurally describe the retainer and should be accorded patentable significance. For example, the language a "channel being configured to retain at least a portion of the medical article within the body member with the retained portion extending entirely through the channel" and "the lower surface being located below the channel and at a distance spaced from the central axis, the distance being greater than a distance between a lower extremity of the retained portion of the medical article and the central axis as measured so as to inhibit contact between at least the lower extremity of the retained portion of the medical article and a patient's skin" found in Claim 32 are not intended use limitations, but serve to describe the structural of the retainer. Limitations of this sort should be given patentable weight.

As Applicant's counsel discussed during the interview, the Federal Circuit, in *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986), gave patentable weight to a limitation similar to the one currently at issue. The patent in *Orthokinetics* claimed a wheelchair that, *inter alia*, was so dimensioned as to fit through the door of an automobile. The Federal Circuit found that this limitation should be given patentable significance, and explained that "[t]he phrase 'so dimensioned' is as accurate as the subject matter permits, automobiles being of various sizes." *Id.* at 1575. The court continued on to state, "The patent law does not

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require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.” *Id.* at 1576.

Similarly, Applicant is not required to list all the possible dimensions of medical articles given the variety of sizes that medical articles may have. The phrases “a channel being configured to”, “at a distance spaced from,” and “greater than a distance between” are as definite as the subject matter permits. The Examiner accordingly agreed that the phrases “channel being configured to”, “at a distance spaced from,” and “greater than a distance between” are limitations agreed at least to consider them when assessing the patentability of the amended claims.

**Rejection under §35 U.S.C. §102(b) over Swauger (U.S. Patent No.5,413,562)**

The Examiner rejected independent Claims 32, 44, 49, 58, and 60 as anticipated by U.S. Patent No. 5,413,562 to Swauger. Applicant respectfully submits that the amendments to these claims further distinguish the recited retainer from the applied art; however, Applicant does not acquiesce to the grounds for the rejections and preserves the right to pursue the original claim language in a continuation application.

Amended Claim 32 is directed to a retainer that includes, among other elements, “at least one support having a lower surface ... being located below the channel and at a distance spaced from the central axis, the distance being greater than a distance between a lower extremity of the retained portion of the medical article and the central axis so as to inhibit contact between at least the lower extremity of the retained portion of the medical article and a patient’s skin when the retainer is placed upon the patient’s skin.” Claims 44, 49, 58, and 60 have been amended along similar lines: Claim 44 now recites, among limitations, the channel is configured to retain at least a portion of the medical article within the body member with the retained portion extending entirely through the channel and means for inhibiting contact between a lower extremity of the retained portion of the medical article and a patient’s skin; Claim 49 states, *inter alia*, that the channel is configured to retain at least a portion of the medical article within the body member with the retained portion extending entirely through the channel ... the channel being located within the body member so that a lower extremity of the retained medical article is spaced at a distance from the central axis that is less than a distance between a lower extremity of the body member and the central axis so as to inhibit contact between the retained portion of the medical article and a patient’s skin; Claim 58 recites, among other limitations, that the channel is

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configured to retain a portion of the medical article within the body member with the retained portion extending entirely through the channel and that a distance between the at least one support and the central axis of the channel is greater than a distance between a lower extremity of the medical article and the central axis so as to inhibit contact between the retained portion of the medical article and a patient's skin; and Claim 60 recites, *inter alia*, that the channel is configured to retain at least a portion of the medical article within the body member with the retained portion extending entirely through the channel, the channel and that the support surface is disposed below the channel and at a distance spaced from the central axis, which is greater than a distance between a lower extremity of the retained portion of the medical article and the central axis so as to inhibit contact between the lower extremity of the retained portion of the medical article and the patient's skin. The applied art fails to disclose at least the recited structures noted above.

U.S. Patent No. 5,413,562 to Swauger discloses a stabilizing fitting for securing a syringe body adjacent to a venipuncture site. As discussed during the interview, the syringe body in Swauger "is forcibly urged against the skin of the patient's limb, and therefore, held in place" by the stabilizing fitting (col. 4, lines 14-16). Thus, the applied art fails to disclose, *inter alia*, the claimed structure of each claim referenced above. As discussed during the interview, the portion of the tubing connected to the syringe body, which lies outside the stabilizing fitting, cannot be considered a "retained portion" as the claims require the retained portion to extend entirely through the channel. Accordingly, Swauger discloses pressing the syringe body, which is contained within the stabilizing fitting, against the patient's skin to restrain the syringe.

In view of the amendments to the independent claims, Applicant respectfully requests reconsideration of Claims 32, 44, 49, 58, and 60. Dependent Claims 33-43, 45-48, 50-51, 59, and 61-78 each depend from one of independent Claims 32, 44, 49, or 58, and thus is patentable for at least the same reasons that support the allowance of the claim from which it depends. Additionally, Applicant has amended the dependent claims in order to improve the clarity of the language used and to improve the claims readability. Accordingly, the amendments to the dependent claims have not been made in response to an outstanding rejection and were not made for reasons relating to patentability.

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**CONCLUSION**

For the foregoing reasons, it is respectfully submitted that the rejection set forth in the outstanding Office Action is inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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